

JUN 21 1986

K961180

SUMMARY OF SAFETY AND EFFECTIVENESS

NMI ANTEGRADE CARDIOPLEGIA CANNULAE

I. General Information

- A. Generic Name: Aortic Root Cannula
- B. Trade Name of Device: NMI Antegrade Cardioplegia Cannula
- C. Applicant's Name and Address: Naltiac Medical, Inc.
17194 Preston Rd, Suite 123-206
Dallas, Texas
- D. Pre-market Notification Number: Not yet assigned

II. Indications for Use

The NMI Antegrade Cardioplegia Cannulae are intended to be used to deliver cardioplegia solutions to the heart or venting cardioplegia away from the heart via the ascending aorta. The cannulae may also be use to aspirate air from the ascending aorta.

III. Device Description

The NMI Antegrade Cardioplegia Cannulae are manufactured in vented and non-vented 12 and 14 gauge. The devices consist of a PVC catheter body with optional vent line, radiopaque flexible PVC tip, stainless steel needle stylet, vent line adapter, polypropylene pinch clamp, PVC suture ring and PVC female luer lock connector.

IV. Device Classification: Class II

V. Safety and Effectiveness

Substantial Equivalence: The device has been shown to be substantially equivalent to the DLP, Inc. Aortic Root Cannulae #K790565A.

VI. Other Safety and Effectiveness Data

Materials: Fluid contact materials of construction comply with Tripartite Biocompatibility Guidance for external devices, blood path direct, short term use.

Sterilization: Validated 100% Ethylene Oxide sterilization cycle (Overkill Method) SAL 10^{-6}

Pyrogenicity: Non-Pyrogenic per USP Pyrogen test (LAL)

Functional Testing

Pressure Drop/Saline

NMI Cannulae average pressure drops range at flow rates between 100 and 500 ml/min= 8 to 45 mmHg @ 4°C

DLP Cannulae average pressure drops range at flow rates between 100 and 500 ml/min= 6 to 63 mmHg @ 4°C

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**Pressure Drop/Saline
Continued**

**NMI Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 3 to
40 mmHg @ 37°C**

**DLP Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 6 to
62 mmHg @ 37°C**

**Pressure Drop/Bovine Blood
(@ 25% Hematocrit)
to**

**NMI Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 10**

66 mmHg @ 4°C

**DLP Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 9 to
93 mmHg @ 4°C**

**NMI Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 5 to
48 mmHg @ 37°C**

**DLP Cannulae average pressure drops range
at flow rates between 100 and 500 ml/min= 9 to
69 mmHg @ 37°C**

Leak Test Requirements:

**No leaks at 10 psi air on NMI device at 4°C and
40°C**

Tubing Bond Strength:

Exceeds 0.4 lb tensile strength @ 4°C and 40°C

Luer Connections:

**Meets ANSI/HIMA MD70.1-1983 for Medical
Materials Luer Tape Fittings**

Package Integrity:

**Tyvek/Polymylar passed burst test per ASTM
F1140-88**

Shipping & Distribution Testing:

**Passed Distribution Simulation Test per ASTM
40169 Standard**

Accelerated Aging:

**One (1) year with no affects on performance
characteristics**